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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/664,871	09/19/2000	Francois Mach	EGYP 3.0-009	5326

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EXAMINER
HUI, SAN MING R

ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 02/26/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/664,871	MACH, FRANCOIS	
	Examiner	Art Unit	
	San-ming Hui	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 December 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6,10,11,15-20 and 35-39* is/are pending in the application.

4a) Of the above claim(s) *38 and 39* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6, 10, 11, 15-20, and 35-37* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

The declaration was filed on December 2, 2002 under 37 CFR 1.131 has been considered but is ineffective to overcome the Partridge reference (US Patent 6,403,637). However, it is sufficient to overcome the obviousness rejection under 35 USC 103(a).

The Partridge reference is a U.S. patent or U.S. patent application publication of a pending or patented application that claims the rejected invention. An affidavit or declaration is inappropriate under 37 CFR 1.131(a) when the reference is claiming the same patentable invention, see MPEP § 2306. If the reference and this application are not commonly owned, the reference can only be overcome by establishing priority of invention through interference proceedings. See MPEP Chapter 2300 for information on initiating interference proceedings. If the reference and this application are commonly owned, the patent may be disqualified as prior art by an affidavit or declaration under 37 CFR 1.130. See MPEP § 718.

The cancellation of claims 7-9, 12-14, and 21-34 in amendments filed December 2, 2002 is acknowledged.

Applicant's amendment filed December 2, 2002 have been entered.

Claims 1-6, 10, 11, 15-20, and 35-39 are pending.

Claims 38, and 39 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected specie, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 9, received January 2, 2002.

This application contains claims 38-39 drawn to an invention nonelected without traverse in Paper No. 9. A complete reply to the final rejection must include cancelation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

The outstanding objections of claims 7, 21, 26, 27, 29, and 32 are withdrawn in view of the amendments filed December 2, 2002.

The outstanding rejections under 35 USC 112, first and second paragraphs are withdrawn in view of the amendments filed December 2, 2002.

Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 1-6, 10, 11, 15-20, and 35-37 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-7, 9-11, 13-16, 18, 20-26, and 31-33 of copending Application No. 09/960471. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

The CD40-mediated anti-immuno-inflammatory effect in a mammal is inherently present in the method of administering a statin compound to the mammal.

Claims 2-6, 10-11, 15-20, and 35-37 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 2-7, 9-11, 13-16, 18, 20-26, and 31-33 of copending Application No. 10/056608, 10/056288, 10/056,645, 10/056,133, and 10/056,606. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

The CD40-mediated anti-immuno-inflammatory effect in a mammal is inherently present in the method of administering a statin compound to the mammal.

Claims 1-6, 10-11, 15-20, and 35-37 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-7, 9-11, 13-16, 18, 20-26, and 31-33 of copending Application No.10/056,646. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

The CD40-mediated anti-immuno-inflammatory effect in a mammal is inherently present in the method of administering a statin compound to the mammal.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-6, 10-11, 15-20, and 35-37 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 36-48 and 76-93 of U.S. Patent No. 10/056608, 10/056288, 10/056,645, 10/056,133, and 10/056,606. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims in the copending applications are drawn to a treatment of inflammatory conditions including rheumatoid arthritis. The only difference is that the claims in the co-pending applications recite the employment of additional anti-rheumatoid agents. One of ordinary skill in the art would have been reasonably expected to employ additional anti-rheumatoid agents to treat inflammation such as rheumatoid arthritis because combining two agents which are known to be useful to treat rheumatoid arthritis individually into a single composition useful for the very same purpose is prima facie obvious. See *In re Kerkhoven* 205 USPQ 1069.

Claims 1-6, 10-11, 15-20, and 35-37 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 36-48 and 76-106 of U.S. Patent No. 10/056,646. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims in the copending applications are drawn to a treatment of inflammatory conditions including rheumatoid arthritis. The only difference is that the claims in the co-pending applications recite the employment of additional anti-rheumatoid agents. One of ordinary skill in the art would have been reasonably expected to employ additional anti-rheumatoid agents to treat inflammation such as rheumatoid arthritis because combining two agents which are known to be useful to treat rheumatoid arthritis individually into a single composition useful for the very same purpose is prima facie obvious. See *In re Kerkhoven* 205 USPQ 1069.

Applicant's remarks regarding the cancellation of the claims in the conflicting applications have been considered but are not found persuasive. There is no evidence of record to show such amendments were actually made to the conflicting applications.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-6, 10, 11, 15-20, and 35-37 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The expression "an MHC Class II-mediated inflammatory or autoimmune disorder characterized by IFN-γ inducible Class II transactivator expression" in the claims renders the claims indefinite as to the autoimmune disease encompassed thereby. It is not clear what conditions would be considered as "an MHC Class II-mediated inflammatory or autoimmune disorder characterized by IFN-γ inducible Class II transactivator expression". Subsequently, it is also not clear what mammal will be encompassed by the claims.

The expression "an autoimmune disease or condition characterized by IFN-γ inducible Class II transactivator expression" in the claims renders the claims indefinite as to the autoimmune disease encompassed thereby. It is not clear what conditions would be considered as "an autoimmune disease or condition characterized by IFN-γ inducible Class II transactivator expression"

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1-3, 6, 11, 15, and 20 are rejected under 35 U.S.C. 102(e) as being anticipated by Partridge (US Patent 6,403,637 B1).

Partridge teaches a method of treating arthritis in a mammal comprising administering an effective amount of atorvastatin to the mammal (See particularly claims 1-13).

Applicants' attention is directed to *Ex parte Novitski*, 26 USPQ2d 1389 (BOPA 1993) illustrating anticipation resulting from inherent use, absent a *haec verba* recitation for such utility. In the instant application, as in *Ex parte Novitski*, supra, the claims herein are directed to achieving MHC Class II immunomodulation with old and well known compounds or compositions and the specific activities of the administration of an old and well known compound, atorvastatin, in cellular level. It is now well settled law that administering compounds inherently possessing a protective utility anticipates claims directed to such protective use. Arguments that such protective use is not set forth *haec verba* are not probative. Prior use for the same utility clearly anticipates such utility, absent limitations distancing the proffered claims from the inherent

anticipated use. Attempts to distance claims from anticipated utilities with specification limitations will not be successful. At page 1391, *Ex parte Novitski*, supra, the Board said "We are mindful that, during the patent examination, pending claims must be interpreted as broadly as their terms reasonably allow. *In re Zletz*, 893 F.2d 319, 13 USPQ2d 1320 (Fed. Cir. 1989). As often stated by the CCPA, "we will not read into claims in pending applications limitations from the specification." *In re Winkhaus*, 52 F.2d 637, 188 USPQ 219 (CCPA 1975).". In the instant application, Applicants' failure to distance the proffered claims from the anticipated prophylactic utility, renders such claims anticipated by the prior inherent use.

Response to Arguments

Applicant's arguments filed December 2, 2002 averring the subjects intend to be treated in the instant invention different from that of the Partridge reference have been fully considered but they are not persuasive. There is no evidence provided by the applicant showing either osteoarthritis patients do not have the herein claimed disease characteristics or rheumatoid arthritis patients do not have the excess amounts of matrix metalloproteinases. Without such showing the herein claimed invention is still considered as properly rejected under 35 USC 102(e).

Article provided by the applicant as Appendix B has been considered, but are not found persuasive to overcome the rejections under 35 USC 102(e). The articles merely lists different types of arthritis without mentioning the underlying

causes of the listed arthritic disorders. Without showing the underlying pathophysiology of the different arthritic disorders, it is not clear what the alleged differences between osteoarthritis and rheumatoid arthritis. Applicant is advised to provide evidence to show the differences between osteoarthritis and rheumatoid arthritis so that it may overcome the anticipation rejection set forth in the instant office action.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to San-ming Hui whose telephone number is

(703) 305-1002. The examiner can normally be reached on Mon 9:00 to 1:00, Tu - Fri from 9:00 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, PhD., can be reached on (703) 305-1877. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

San-ming Hui
February 24, 2003

RUSSELL TRAVERS
PRIMARY EXAMINER
GROUP 1200